DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

NOV 29 2000

WARNING LETTER

VIA FEDERAL EXPRESS

REF: OC:I1-1880

Mr. James Chen
President
Sampo Corporation of America
13311 Brooks Drive, Suite C
Baldwin Park, California 91706

Dear Mr. Chen:

The Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), has completed its review of the FDA's Winchester Engineering and Analytical Center (WEAC) laboratory test of a Sampo brand television product, model SME-32HD5, serial number FDA00012, chassis family C-36D5, manufactured August 2000.

Our review of the test results reveals that the above mentioned television product manufactured by your firm is in violation of section 538 of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C - Electronic Product Radiation Control, and Title 21 of the Code of Federal Regulations (CFR) 1020.10.

CDRH has determined that all products in chassis family C-36D5 fail to comply with the Federal Performance Standard for Television Receivers, 21 CFR 1020.10, and associated regulations as follows:

> 21 CFR 1020.10(c)(1) - The WEAC analysts were able to measure x-radiation above the 0.5 mR/hr exposure rate limit, 0.63 and 0.87 mR/hr, under test conditions specified in 21 CFR 1020.10(c)(3)(iii).

WEAC analysts found a different worst case fault, D6C7 open, in the hold-down safety circuit, than Sampo's reported worst case fault. By disabling D6C7, the WEAC analysts were able to raise the high voltage above the hold-down activation point. The analysts also noted from Sampo's data for this unit that it included: 1) an incorrect graph of the isoexposure rate limit curve (IRLC) for the cathode ray tube, 2) an incorrect graph of Sampo's data from Attachments J1 and J4, 3) improper usage instructions for the qualitative x-radiation survey meter, 4) inconsistent radiation limits for corrective action at Sampo, and 5) inconsistent instructions for high voltage adjustment during fault testing. For a more detailed explanation of testing, please refer to the enclosed copy of the WEAC laboratory analysis.

Further distribution of television products in this chassis family into United States (U.S.) commerce must be discontinued until these deviations are resolved. Section 538(a)(1) and (a)(5) of the Act prohibits any manufacturer (including importers) from certifying or introducing into commerce electronic products that do not comply with an applicable standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports.

You must respond in writing within 15 days of receipt of this letter to one of the options listed below. In your response, you must also provide the number of the referenced products that have been produced, the number of such products that have left the place of manufacture, and the number that have been shipped to the United States (U.S.). In addition, if the product distribution was confined to specific geographical areas of the U.S., please specify those areas.

1. Refutation - You may submit your views and evidence in accordance with 21 CFR 1003.11 to establish that the alleged non-compliance does not exist, or does not relate to the safety of the product.

2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31). Also, indicate all models and brands that are to be covered by the exemption along with the number produced and dates of production.

3. Purchaser Notification and Corrective Action - If you neither refute the non-compliance nor request an exemption, then you must (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products at no charge to the user.

    a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the CDRH. It is recommended that you submit a draft of this letter to us for review.

b. Corrective Action Plan (CAP) - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, and 1004.4.

Failure to respond to this letter or to correct these products in a timely manner can result in regulatory action being initiated by the FDA without further notice. These actions may include an injunction and/or imposition of civil penalties as provided for in section 539 of the Act. Persons failing to correct violations are subject to civil penalties of up to $1,000 per violation and up to a maximum of $300,000 without further notification by the FDA.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required by 21 CFR 1003.11(c) and 1003.21 to proceed with interim notification to affected persons. Therefore, you are encouraged to immediately begin your preparation of an accurate user location list.

When you investigate this case you should also consider other similar models. If other models made by your company are subject to the same non-compliance, you must notify FDA as required under 21 CFR 1003.10.

When Sampo has submitted sufficient information on the changes to the current testing program and product design that enables the CDRH to determine whether or not the testing program is adequate to ensure compliance and the modified product complies, Sampo may resume the certification of the subject products. The CDRH will advise you whether the information you submit is satisfactory and when you may resume introduction into U.S. commerce of certified products, in this chassis family.

Your response should reference the case number assigned, I1-1880, and should be sent to: Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a copy of your response to this letter to: Food and Drug Administration, Director, Compliance Branch, 222 W. 6th Street, San Pedro, California 90731.

If you have any questions about this letter or the regulations, please contact Dr. Edward Dawson of the Electronic Products Branch at (301) 594-4654 or by facsimile at (301) 594-4672.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure

cc: Mr. Felix Chen
President
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Pan Chiao, Taipei Hsien, Taiwan
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